No. 98-1152

IN THE
# Supreme Court of the United States
OCTOBER TERM, 1998

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FOOD AND DRUG ADMINISTRATION, *et al.*,
*Petitioners,*

v.

BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
*Respondents.*

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**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit**

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## RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

Whether the Food and Drug Administration has jurisdiction to regulate the continued marketing of tobacco products, despite the facts that (1) its governing statute requires it to ban "unsafe" products, and (2) Congress has enacted a series of tobacco-specific statutes, which are premised on the continued marketing of tobacco products and which provide no role for FDA? *

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* FDA's assertion of jurisdiction relates to cigarettes and smokeless tobacco products. *See* 21 C.F.R. § 897.1(a) (1998). All references herein to "tobacco products" are to cigarettes and smokeless tobacco products "as customarily marketed." The words "as customarily marketed" are FDA's. Letter from Mark Novitch for FDA Comm'r Jere Goyan 12 (Nov. 2[illegible], 1980) (FDA Dkt. Nos. 77P-0185, 78P-0338/CP). Those words refer to the marketing of cigarettes and smokeless tobacco products with the customary claims (*e.g.*, "smoking satisfaction," "good taste"), in contrast to claims of a health benefit.

## RULE 29.6 LISTING

Pursuant to Supreme Court Rule 29.6, Respondents submit the following corporate information:

1. Acme Retail, Inc., has no parent companies and has no nonwholly owned subsidiaries.

2. The parent companies of Brown & Williamson Tobacco Corporation are:

British American Tobacco p.l.c.
British American Tobacco (1998) Limited
BAT Industries p.l.c.
British American Tobacco (Holdings) Limited
Louisville Securities Limited
BATUS Holdings Inc.
BATIC, Inc.
BATUS Tobacco Services, Inc.

Brown & Williamson Tobacco Corporation has no nonwholly owned subsidiaries.

3. Central Carolina Grocers, Inc., is a North Carolina corporation which is owned by one hundred ten (110) individuals and entities, none of whom individually own ten percent (10%) or more of the capital stock of the corporation. Central Carolina Grocers, Inc., has no nonwholly owned subsidiaries.

4. The parent companies of Conwood Company, L.P., are:

Asworth Corporation
Conwood LLC
HT Forum, Inc.
Dalfort Aviation Services, Inc.

Conwood Company, L.P., has no nonwholly owned subsidiaries.

5. Coyne Beahm, Inc., has no parent companies and has no nonwholly owned subsidiaries.



6. J.T. Davenport, Inc., has no parent companies and has no nonwholly owned subsidiaries.

7. The parent companies of Lorillard Tobacco Company are Lorillard, Inc., and Loews Corporation. Lorillard Tobacco Company has no nonwholly owned subsidiaries.

8. National Association of Convenience Stores has no parent companies and has no nonwholly owned subsidiaries

9. The parent company of National Tobacco Company, L.P., is North Atlantic Trading Company, Inc. National Tobacco Company, L.P., has no nonwholly owned subsidiaries.

10. North Carolina Tobacco Distributors Committee, Inc., has no parent companies and has no nonwholly owned subsidiaries.

11. The parent company of Philip Morris Incorporated is Philip Morris Companies, Inc. Philip Morris Incorporated has no nonwholly owned subsidiaries.

12. The parent companies of The Pinkerton Tobacco Company are Swedish Match AB and Swedish Match North America Inc. The Pinkerton Tobacco Company has no nonwholly owned subsidiaries.

13. R.J. Reynolds Tobacco Company is the indirect subsidiary of RJR Nabisco Holdings Corp. (R.J. Reynolds Tobacco Company is wholly owned by RJR Nabisco, Inc., which is wholly owned by RJR Nabisco Holdings Corp., which is publicly held). Nabisco Holdings Corp. is the publicly held affiliate of R.J. Reynolds Tobacco Company.

The subsidiaries of R.J. Reynolds Tobacco Company that are not wholly owned are:

AOISMA
AO3T Kabisco

Camel Racing Inc.-Courses Camel Inc.
China-American Cigarette Company Limited
Modi RJR Limited
OAO Electronmash
R.J. Reynolds Berhad
R.J. Reynolds-Da Nang Tobacco Company Limited
R.J. Reynolds Espana, S.L.
R.J. Reynolds/M.C. Tobacco Company, Limited
R.J. Reynolds Tobacco Baku
R.J. Reynolds Tobacco Kazakhstan
R.J. Reynolds Tobacco-Kremenchuk
R.J. Reynolds Tobacco Lviv ISC
Reynolds Manufacturing (Bulgaria) Ltd.
Reynolds Manufacturing (Romania) S.A.
RJR-Armavirtabak, OAO
RJR Tobacco Yelets., OAO
Tabandor S.A.
Tanzania Cigarette Company
TOO RJR-Petro

On March 9, 1999, R.J. Reynolds Tobacco Company and its parent company, RJR Nabisco Holdings Corp., announced that they had entered into a definitive agreement to sell their international tobacco business to Japan Tobacco, Inc. The non-wholly owned subsidiaries of R.J. Reynolds Tobacco Company identified in this disclosure are part of the international tobacco business that is to be sold. The companies expect the sale to be completed approximately sixty (60) days after the announcement.

On March 9, 1999, RJR Nabisco Holdings Corp. also announced that its Board of Directors had approved a plan to separate R.J. Reynolds Tobacco Company from its Nabisco food business. The separation will be accomplished by a spin-off to RJR Nabisco Holdings Corp. shareholders of shares in R.J. Reynolds Tobacco Company. After the spin-off, RJR Nabisco Holdings Corp.



and RJR Nabisco, Inc., will no longer be parent companies of R.J. Reynolds Tobacco Company. The spin-off is anticipated to occur as soon as practicable after the sale of the international tobacco business.

14. The parent company of Swisher International, Inc., is Swisher International Group, Inc. Swisher International, Inc., has no nonwholly owned subsidiaries.

15. The parent company of United States Tobacco Company is UST Inc. United States Tobacco Company has no nonwholly owned subsidiaries.

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## INTRODUCTION

The Government argues that failure to overturn the court of appeals' decision "will deprive the public of an unparalleled opportunity to prevent millions of children from" using tobacco. Petition for a Writ of Certiorari ("Pet.") 15-16.

To the contrary, "the public"—through its elected representatives in Congress—has already addressed the complex and highly political issues of tobacco and health, including underage access. In a series of tobacco-specific statutes in 1965, 1970, 1983, 1984, 1986, and 1992, Congress crafted a national regulatory policy premised on the continued availability of tobacco products, even though they are deemed to be unsafe. *See, e.g.*, 15 U.S.C. § 1331 (this and other relevant statutes are included in Respondents' Appendix). Congress gave FDA no role in the administration of these statutes or this policy. Far from seeking to preserve the public's opportunity to regulate tobacco, FDA simply seeks to supplant enacted policy by disregarding statutes with which it disagrees and short-circuiting an on-going political process.

There is no reason to grant the writ. The decision of the court of appeals is correct. It properly applied the relevant precedents of this Court and correctly interpreted the relevant statutes. It does not conflict with any decision of this Court or any other court.[1] Its scope is limited. It addresses only the question of FDA's jurisdiction over tobacco products. It does not affect FDA's authority with respect to the kinds of products FDA has historically regulated; nor does

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[1] Indeed, it is consistent with the two closest appellate decisions, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980) (upholding FDA's denial of jurisdiction over tobacco products), and *FTC v. Liggett & Myers Tobacco Co.*, 203 F.2d 955 (2d Cir. 1953), *aff'g on opinion below*, 108 F. Supp. 573 (S.D.N.Y. 1952) (interpreting language in FTC Act identical to that in Food, Drug, and Cosmetic Act as not covering tobacco products).

it affect the regulation of tobacco products under other laws.[2]

## COUNTER-STATEMENT

The Petition neglects: (i) the critical differences between the public policy issues raised by tobacco products and those raised by the products historically regulated by FDA, (ii) Congress's enactment of statutes specifically designed to address the distinctive issues tobacco products raise, (iii) FDA's advice to Congress that the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") does not apply to tobacco products and would ban them if it did, (iv) the extensive regulation of tobacco products under other federal and state laws, and (v) the current congressional attention to this issue.

1. For most of this century, tobacco and tobacco products have constituted a major and separate sector of the nation's economy.[3] In the 1930s, when Congress was considering the FDCA, cigarettes were smoked by approximately 37% of the adult population. U.S. Dep't of Health & Human Servs., *The Health Consequences of Smoking to Women* 23 (1980). Today, they are smoked by about 23% of adults, nearly 50 million people. Centers for Disease Control and Prevention, *Morbidity & Mortality*

[2] The Petition refers frequently to the restrictions on advertising in FDA's tobacco rule. Yet, the Government does not seek review of the question of FDA's statutory authority to regulate tobacco product advertising. Nor could it. Although the district court held that FDA's advertising regulations were not authorized by 21 U.S.C. § 360j(e), the court of appeals was careful to vacate that judgment and state that it expressed no view on the matter. Pet. App. 54a n.29. The constitutional challenge to those regulations was not reached by the district court, *see id.* at 134a n.33, and, of course, was not addressed by the court of appeals.

[3] *See, e.g.*, U.S. Dep't of Commerce, *Statistical Abstract of the United States*, *passim* (1938) (separate statistics for tobacco sector); Technical Committee on Industrial Classification, Executive Office of the President, 1 *Standard Industrial Classification Manual* xi, 8, 25 (1941) (separate SIC codes for tobacco products).



*Weekly Report* (Nov. 6, 1998). Tobacco is critical to the economies of certain States and communities. Consequently, establishing national tobacco policy has always been a *political* task for Congress.

2. From the beginning of this century, there has been widespread concern that tobacco adversely affects health.

Between 1895 and 1921, 14 States banned cigarettes; and all the others enacted prohibitions on their sale to minors.[4] In *Austin v. Tennessee*, 179 U.S. 343, 348 (1900), this Court, in upholding a ban, observed that "belief in [cigarettes'] deleterious effects . . . has become very general." This Court has noted that "physicians had suspected a link between smoking and illness for centuries," and "the first medical studies of that connection" appeared in the 1920s. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992).

Given these longstanding concerns, Congress could not have assumed that tobacco products could meet the requirement embodied in the FDCA in 1938 that drugs be affirmatively shown to be safe in order to be distributed. *See* FDCA § 505(d)(2), Pub. L. No. 75-717, § 505 (d)(2), 52 Stat. 1040, 1052 (1938) (codified at 21 U.S.C. § 355(d)(2)). Moreover, tobacco products cannot be marketed as medical products under the FDCA because they do not provide any *therapeutic* benefits that FDA would view as justifying their risks.

Prohibition of alcohol ended in 1933, the year Congress began considering what was to become the FDCA. The idea that Congress in 1938 intended to give an administrative agency the power on its own to institute a new Prohibition defies common sense.

[4] Elaine Nuehring & Gerald E. Markle, *Nicotine and Norms: The Re-Emergence of a Deviant Behavior*, 21 Social Problems 513, 515 (1974); 1899 Tex. Gen. Laws Ch. 139, § 1 (codified at Tex. Penal Code art. 1049 (1911)).

In 1964, the landmark first Surgeon General's Report on Smoking and Health concluded that cigarettes have serious adverse effects on the body. U.S. Dep't of HEW, *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964). The Report described some tobacco use as similar to "drug habituation," which is "reinforced and perpetuated by the pharmacological actions of nicotine on the central nervous system." *Id.* at 350, 354. The published studies cited in the report made these effects foreseeable and, therefore, under FDA's present interpretation of 21 U.S.C. §§ 321(g)(1)(C) and 321(h)(3), "intended."

In 1970, Congress required that cigarette packs and cartons state: "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health." Pub. L. No. 91-222, § 4, 84 Stat. 87, 88 (1970). This warning further reflected the consensus among public health authorities that cigarettes have foreseeable adverse effects on the body. *See Larus & Brother v. FCC*, 447 F.2d 876 (4th Cir. 1971) (upholding FCC action based on that consensus).

3. Thus, owing to their widespread use, national and regional economic importance, perceived risks, and lack of therapeutic benefits, tobacco products have long presented public policy issues very different from those presented by foods, drugs, medical devices, and cosmetics. These circumstances help explain why neither the text of the 1938 FDCA nor its legislative history mentions tobacco products or the distinctive issues they raise.

4. FDA's contemporaneous interpretation of the FDCA, even before the enactment of any of the tobacco-specfic statutes, was that the FDCA does not apply to tobacco products. In defending that interpretation, the Government pointed out:



> After the passage of the 1938 Act, FDA repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of the term "drug" absent health claims on behalf of the manufacturer or vendor. . . . These records . . . includ[e] correspondence dating from at least as early as 1940. . . .

Brief for Gov't Appellee (FDA) 16, 22 n.19, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

In 1963, FDA explained its interpretation:

> 1. The statutory basis for the exclusion of tobacco products from FDA's jurisdiction is the fact that tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the [FDCA] for food, drug, device or cosmetic.
>
> 2. Congress did not consider problems that might arise from the use of tobacco when it considered the bills during the 1933-38 period, which led to the enactment of the [FDCA].

Memorandum from FDA Bureau of Enforcement to Directors of Bureaus and Divisions and Directors of Districts (May 23, 1963), *reprinted in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92d Cong. 240 (1972).

5. In response to the 1964 Surgeon General's Report, Congress enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), Pub. L. No. 89-92, 79 Stat. 282 (1965), which established a separate regulatory program for tobacco, and provided no role for FDA. In developing the FCLAA, Congress focused, for the first time, on whether to authorize FDA to regulate tobacco products. At that crucial time, both the Department of Health, Education, and Welfare ("HEW") and FDA told Congress that the FDCA gave the agency no jurisdiction.

Surgeon General Luther Terry testified: "[W]e do not have such authority [*i.e.*, over the labeling or advertising

of cigarettes] in existing laws governing the Public Health Service and [FDA]." *Cigarette Labeling & Advertising Relative to Health Problems Associated with Smoking: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 88th Cong. 56 (1964) ("*1964 House Hearings*"). FDA testified: "The [FDA] has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Cigarette Labeling and Advertising—1965: Hearings Before the House Comm. on Interstate and Foreign Commerce*, 89th Cong. 193 (1965) ("*1965 House Hearings*") (testimony of FDA Ass't Comm'r Winton Rankin).[5] In light of this testimony, Congress had no reason to amend the FDCA to exclude tobacco products.

Two bills proposed to give FDA jurisdiction under the FDCA. *See 1964 House Hearings* 4-5 (H.R. 5973), 6-7 (H.R. 9512). HEW Secretary Anthony J. Celebreeze advised that such jurisdiction "might well" lead to a ban, a result he characterized as not intended and not acceptable to the American people. *Id.* at 18. The proposal was abandoned without controversy. *See 1965 House Hearings* 29.

Instead, Congress embodied in the FCLAA a new regulatory program for tobacco, outside the FDCA and premised on the continued availability of tobacco products:

> It is the policy of the Congress, and the purpose of this Act, to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

[5] This testimony was also referred to in the Senate. 111 Cong. Rec. 13431 (June 16, 1965). The position that FDA's jurisdiction depends on claims was not unique to tobacco products, but, rather, reflected general food and drug law. Despite occasional contrary dicta over the decades, no court has ever held that a product is a "drug" or medical "device" in the absence of a therapeutic claim for the product. *See* Pet. App. 19a (quoting the district court, Pet. App. 107a).



> (1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and
>
> (2) *commerce and the national economy may be* (A) *protected to the maximum extent consistent with this declared policy* and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

FCLAA § 2, Pub. L. No. 89-92, § 2, 79 Stat. 282, 282 (codified as amended at 15 U.S.C. § 1331) (emphasis added). Congress has amended the FCLAA twice, but has retained Section 1331 essentially unchanged, and has never given FDA any role in the tobacco regulatory program.[6]

6. The FDCA does not equip FDA to administer the policy stated in Section 1331. The FDCA mandates that all marketed drugs and medical devices be therapeutically effective and safe, *see* Pet. App. 20a-29a; *see also* 21 U.S.C. § 393(b)(2)(B)-(C), and does not provide for "protect[ion of]" "commerce and the national economy . . . to the maximum extent consistent with [the giving of warnings]."

To protect the balance expressed in Section 1331, the FCLAA also prohibits any federal agency from requiring on cigarette packages any "statement relating to smoking and health" different from the warnings prescribed in the FCLAA, 15 U.S.C. § 1334(a). A parallel provision applies to smokeless tobacco products. *See id.*

[6] In 1984, when amending the FCLAA's provisions on warnings, Congress reaffirmed Section 1331 by keeping it intact and, to conform paragraph (1) to the revised warnings, amending it to read: "the public may be adequately informed about any adverse health effects of cigarette smoking by inclusion of warning notices on each package of cigarettes and in each advertisement of cigarettes. . . ." Pub. L. No. 98-474, § 6(a), 98 Stat. 2200, 2204 (1984) (codified at 15 U.S.C. § 1331).

§ 4406(a). These provisions preclude FDA from requiring on tobacco products the kind of directions for safe use that are central to FDA's regulation of all drugs and medical devices sold over-the-counter to consumers. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. §§ 201.5, 801.5 (1998).

7. Since 1965, Congress has continually responded to evolving public concerns about tobacco and health by enacting new statutes, which have expanded its tobacco regulatory program.

In 1970, Congress amended the FCLAA by, *inter alia*, changing the warning on cigarette packages, and, to reduce underage smoking, by banning cigarette advertising on television and radio. *See* Pub. L. No. 91-222, 84 Stat. 87 (1970).

In 1983, Congress directed the Secretary of Health and Human Services ("HHS") to report to Congress every three years on research findings on "the addictive property of tobacco," and to include recommendations for legislation and administrative action. Pub. L. No. 98-24, § 505(b)(2)-(3), 97 Stat. 175, 178 (1983) (codified at 42 U.S.C. § 290aa-2(b)(2)-(3)).

In 1984, Congress again amended the FCLAA, to require four rotating warnings on cigarette packages and advertisements, disclosure of tobacco ingredients to HHS, and the establishment of an Interagency Committee on Smoking and Health, which does not include FDA. *See* Pub. L. No. 98-474, 98 Stat. 2200 (1984).

In 1986, the Comprehensive Smokeless Tobacco Health Education Act created for smokeless tobacco products a regulatory program similar to that for cigarettes under the FCLAA. *See* Pub. L. No. 99-252, 100 Stat. 30 (1986).

In 1992, Congress addressed underage access to tobacco products. The statute embodied a two-part strategy: (i) it left the initiative with the States, exercising



their traditional police power; and (ii) it provided financial incentives to the States to increase the effectiveness of their restrictions on underage access. *See* Pub. L. No. 102-321, § 202, 106 Stat. 323, 394 (1992) (codified at 42 U.S.C. § 300x-26).

8. During this entire period, FDA repeatedly reiterated its position that it had no jurisdiction over tobacco products.

In 1972, FDA testified that an assertion of jurisdiction over tobacco products would lead to a ban—a result FDA characterized as not intended by Congress:

> [C]igarettes recommended for smoking pleasure are beyond the [FDCA]. . . . [I]f cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. . . . [The FCLAA] . . . demonstrates that the regulation of cigarettes is to be the domain of Congress. . . . In sum, labeling or banning cigarettes is a step that can be take[n] only by Congress. Any such move by FDA would be inconsistent with the clear congressional intent.

*Public Health Cigarette Amendments of 1971, Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92d Cong. 242 (1972) (testimony of FDA Comm'r Charles Edwards). Thus, FDA recognized that: (i) ordinary tobacco products lie beyond the FDCA as a definitional matter; (ii) tobacco products, if made subject to the FDCA, could not satisfy its requirements for the marketing of medical products; and (iii) the FCLAA confirms Congress's exclusive responsibility for dealing with the health risks associated with tobacco use.

In 1977, Action on Smoking and Health ("ASH") petitioned FDA to regulate cigarettes as "drugs" or "devices" on the ground that their nicotine produces a "phy-

sical addiction" in many smokers, including those who begin smoking when young. *Citizen Petition*, FDA Dkt. No. 77P-0185, at 4-10 (May 26, 1977).

As FDA now asserts, ASH then asserted that: (1) cigarettes and nicotine are drugs, *id.* at 2; (2) cigarettes affect the structure and function of the body, *id.* at 2, 7; (3) studies demonstrate that many smokers smoke for the "physiological effects the drug causes on their body," *id.* at 2; (4) numerous studies demonstrate that nicotine has effects similar to those of heroin and other addictive substances, *id.*; (5) studies since 1940 indicate that smoking is a method of "administering a carefully controlled dose of nicotine to the body," *id.* at 8; (6) a "cigarette is, after all, an instrument, apparatus, or contrivance designed to administer controlled amounts of nicotine and other substances to the smoker upon demand," *id.* at 31; and (7) children have easy access to tobacco, *id.* at 36.

FDA did not dispute *any* of ASH's factual presentations. Rather, it denied the petition on the ground that they could not be a basis for FDA jurisdiction.[7] FDA stated that its 'interpretation of the . . . [FDCA] consistently has been that cigarettes are not a drug unless health claims are made by the vendors." Letter from Comm'r Donald Kennedy to John F. Banzhaf, III, at 3 (Dec. 5, 1977) (FDA Dkt. No. 77P-0185).

When ASH sought judicial review, the Government responded:

> Since at least the issuance of the Surgeon General's Report on Smoking in 1964, cigarettes have been at the forefront of discussions of the public health—in Congress, in the Executive Branch, in the news media, and among the public generally. The participants in these discussions over the past 15 years

[7] FDA's 1977 decison rejected only ASH's claim that cigarettes are "drugs." FDA rejected ASH's claim that they are devices in denying ASH's second petition, discussed at pp. 11-12, *infra*.



> or more would be shocked to learn that during this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them.

Brief for Government Appellee 40, *ASH*, 655 F.2d 236. The court of appeals agreed that, "if the [FDCA] requires expansion [to cover cigarettes], it is the job of Congress." 655 F.2d at 243.

In 1978, ASH again petitioned FDA. *Citizen Petition*, FDA Dkt. No. 78P-0338/CP (Oct. 2, 1978). It claimed that filtered cigarettes are medical "devices" under the FDCA. While that petition was pending, the National Institute on Drug Abuse ("NIDA") issued a report finding that "cigarette smoking should be considered a form of addiction, and tobacco in the form of cigarettes, an addicting substance."[8] Indeed, as Dr. William Pollin, the Director of NIDA, later testified: "The conclusion that cigarette smoking behavior is an addictive disorder . . . became *confirmed internationally* back in 1979." *Smoking Prevention Health and Education Act of 1983: Hearings Before the Senate Comm. on Labor and Human Resources*, 98th Cong. 58 (1983) (emphasis added).

Nevertheless, again without rejecting any of ASH's factual presentations, FDA concluded in 1980 that cigarettes are not "devices." Having reviewed the Medical Device Amendments of 1976 and their legislative history, FDA concluded, in unusually strong terms: "It is, therefore, not reasonable to consider cigarettes as 'devices' when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes." Letter from Mark Novitch for FDA Comm'r Jere Goyan 3

[8] National Institute on Drug Abuse, Technical Review on Cigarette Smoking as an Addiction, Final Report (1979), *reprinted in Comprehensive Smoking Prevention Education Act: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 97th Cong. 340, 346 (1982).

(Nov. 25, 1980) (FDA Dkt. Nos. 77P-0185, 78P-0338/CP). FDA also stated: "Insofar as rulemaking would relate to cigarettes . . . as customarily marketed, we have concluded that FDA has no jurisdiction under [the FDCA]. Therefore, no rulemaking is permissible as a matter of law." *Id.* at 12.[9]

In 1988, FDA explained to Congress how nicotine in therapeutic products is within FDA's jurisdiction, but nicotine in tobacco products is not:

> Tobacco products, as they have been customarily marketed, have not been considered by FDA to be within any of the categories of articles over which we have jurisdiction. . . . [C]igarettes or other tobacco products can be "drugs" if the manufacturer or vendor were to make medical claims for the product. . . .
>
> On the other hand, [a product] which does not contain tobacco but instead contains nicotine, the principal pharmacological agent found in tobacco, is regarded as a "drug" because the manufacturer clearly intended and labeled it as a smoking deterent to satisfy a nicotine dependence.

*Health Consequences of Smoking: Nicotine Addiction: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong. 17-19 (1988) (testimony of FDA Comm'r

[9] The view that the FDCA does not provide authority suitable to the regulation of cigarettes was echoed as recently as 1994 by FDA Commissioner David Kessler, who testified that "[t]he tools are limited," and that an assertion of jurisdiction by FDA could have "enormous social consequences." *Regulation of Tobacco Products (Part 1): Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103d Cong. 68-69 (1994). Commissioner Kessler stated that, on this issue, FDA was "seek[ing] guidance from the Congress." *Id.* at 33. Immediately after the 1994 elections changed the political control of Congress, however, FDA decided to proceed on its own. *See* Letter from Diane E. Thompson, FDA Assoc. Comm'r for Legislative Affairs, to Hon. Martin Lancaster 2 (Nov. 10, 1994).



Frank Young). This statement also explains why "stimulants, tranquilizers, appetite suppressants, nicotine replacement products, and narcotics used to treat addiction," Pet. 18, are within FDA's jurisdiction, but tobacco products are not.

None of FDA's statements disavowing jurisdiction relied on policy, discretion, or lack of evidence.[10] Moreover, before 1995, FDA never tried to subject *any* tobacco product to ongoing regulation.[11] Rather, until the rulemaking now at issue, the agency's consistent view was that tobacco products are outside its jurisdiction *as a matter of law and congressional intent.*

9. The regulation of tobacco products is extensive and growing—apart from FDA. Many federal statutes address the health concerns relating to tobacco:

- Congress has addressed underage access to tobacco products by requiring HHS to condition federal funding of certain state programs on the adoption

[10] FDA now seeks to explain its past disavowals as due to ignorance of "recently-discovered evidence" that tobacco companies: (i) knew that nicotine is addictive and (ii) designed their products to deliver precise amounts of nicotine. Pet. 5, 26. Even if taken at face value, however, this "evidence" is the same type of "evidence" FDA previously rejected, as a matter of law, as not a basis for jurisdiction. ASH's 1977 Petition alleged that nicotine was addictive (and the 1964 Surgeon General's Report referred to tobacco use as a "habituation" due to nicotine's "pharmacological actions") and that cigarettes are used by smokers and "designed [by manufacturers] to administer controlled amounts of nicotine," factual allegations FDA viewed as irrelevant. *See* pp. 4, 10, *supra*.

[11] In the 1950s, FDA did drive off the market two cigarette products that made therapeutic claims. *See United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959); *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953). However, the theory of those cases did not relate particularly to tobacco products, and would have applied to *any* consumer product that made such claims. *See, e.g., United States v. 23 . . . Articles, etc.*, 192 F.2d 308 (2d Cir. 1951) (phonograph records that claimed to induce sleep were medical devices).

and enforcement by each State of an 18-year-old minimum purchase age. *See* 42 U.S.C. § 300x-26.

- Congress has banned advertisements of tobacco products from any electronic medium, including television and radio, subject to the jurisdiction of the Federal Communications Commission. *See* 15 U.S.C. §§ 1335, 4402(f).
- Congress has designated the Federal Trade Commission ("FTC") to oversee compliance with statutory requirements for warning labels on all tobacco packages and in all tobacco product advertisements. *See* 15 U.S.C. §§ 1333(a)(1), 4402 (a)-(d).[12]
- Congress has directed the FTC to report annually to Congress about tobacco product advertising, and to recommend legislation on that subject. *See* 15 U.S.C. §§ 1335a, 4403.
- Congress requires tobacco product manufacturers to disclose to HHS annual lists of ingredients used in tobacco products and requires HHS to review the lists and to report to Congress on any perceived health effects. *See* 15 U.S.C. §§1335a, 4403.[13]
- Congress has banned smoking on airplanes, *see* 49 U.S.C. § 41706, and in schools that receive federal funds, *see* 20 U.S.C. § 6083.
- Congress has directed HHS to transmit to Congress reports that describe current research findings on the asserted addictive property of tobacco and that recommend legislation or administrative action. *See* 42 U.S.C. § 290aa-2.

[12] The FTC also regulates advertising of tobacco products under the Federal Trade Commission Act. *See* 15 U.S.C. §§ 41-64.

[13] Thus, Congress has already provided a means to address the Government's concern about a potentially hazardous ingredient in a tobacco product. Pet. 28.



- Congress has directed HHS to report annually to Congress on current information about the health consequences of using tobacco products, and to include any recommendations for legislation. *See* 15 U.S.C. §§ 1337(a), 4407(a).
- Congress has directed HHS to analyze and publish research on the reported health effects of smoking, *see* 15 U.S.C. § 1341(a); it is assisted in that effort by an Interagency Committee on Smoking and Health, *see* 15 U.S.C. § 1341(b).

Thus, the tobacco-specific statutes do not address "narrow issues," Pet. 27, or "different issues" from those addressed by FDA's regulations, *id.* at 20. They address, *inter alia*, underage access, advertising, and labeling, in the manner chosen by Congress. These are the very concerns FDA asserts as the bases for its late entry into this field.

In addition, hundreds of state and local laws restrict the sale of tobacco products to prevent access by minors. Every State prohibits the sale of tobacco products to persons under age 18. In response to varying circumstances and public preferences, the States have enacted a variety of additional provisions relating to proof of age for purchase, licensing of tobacco retailers, product displays, vending machines, and product samples.

Finally, the Government, itself, raises the fact that nearly all the States have entered into a Master Settlement Agreement ("MSA") with the principal tobacco product manufacturers. *See* Pet. 16, 29 n.9.[14] That agreement establishes significant restrictions on tobacco advertising,

[14] The settlement appears at <http://www.naag.org/tob2.htm>. It has been entered into by all 46 States that had not previously settled with the industry, and by the District of Columbia and five territories. The settling cigarette manufacturers account for over 99% of the U.S. cigarette market. United States Tobacco Company, which entered into a parallel agreement with 45 States, the District of Columbia, and five territories, accounts for approximately 55% of the U.S. smokeless tobacco category.

which are embodied in judicially enforceable consent decrees immune from constitutional or statutory challenge.

The MSA contains numerous provisions that address many of the subjects of FDA's regulations. These include: prohibitions against targeting youth and against use of cartoon characters; sweeping restrictions on outdoor tobacco advertising; a prohibition against certain brand-name sponsored events; and a ban on the distribution of non-tobacco merchandise with the brand name, logo, or trademark of a tobacco product. It also bars manufacturers from distributing free samples of tobacco products, except in adult-only facilities. *See* MSA § III (a)-(g).

These tobacco-control initiatives can be evaluated by Congress as it considers whether to enact new legislation to dramatically extend FDA's authority to include tobacco products.

10. Legislation relating to FDA jurisdiction over tobacco products was considered on the Senate floor and in House hearings in the 105th Congress;[15] and the President, in his recent State of the Union Address, called for such legislation in the 106th Congress, *see* 145 Cong. Rec. H258, H260 (daily ed. Jan. 19, 1999). Thus, the question whether to grant FDA jurisdiction over tobacco products is actively before Congress.

## REASONS FOR DENYING THE WRIT

1. FDA contends that it has the authority to ban tobacco products, and that the exercise of that authority

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[15] *See, e.g.*, 144 Cong. Rec. S4883 (daily ed. May 14, 1998) (motion to consider tobacco bill); *id.* at S6433-85 (daily ed. June 17, 1998) (point of order against bill sustained); *The Tobacco Settlement: Views of the Administration and the State Attorneys General: Hearings Before the House Comm. on Commerce*, 105th Cong. (1997); *The Tobacco Settlement—Part 3: Hearings Before the Subcomm. on Health and Environment of the House Comm. on Commerce*, 105th Cong. (1998).



is a matter of its discretion. *See* 61 Fed. Reg. 44,396, 44,405, 44,412-13 (1996); 60 Fed. Reg. 41,314, 41,349, 41,523-24 (1995). Even as it was deciding whether it had jurisdiction, FDA seriously considered whether to ban tobacco products, and found the question a "close" one. 61 Fed. Reg. 44,416. For now, it has rejected a ban because a ban would "overwhelm[]" the health care system by the need to treat smokers, and a "black market and smuggling would develop. . . ." Pet. 23 (citing 61 Fed. Reg. 44,413).

These very grounds, presented to show that "[FDA's] public health policy conclusion [not to ban tobacco products] was well-founded," Pet. 23, demonstrate that FDA has overreached. Not merely "public health policy" considerations, but also law enforcement, national and regional economics, federal and state tax revenues, public preferences, and other factors, would have to be weighed in deciding whether to ban tobacco products. This multifaceted issue far transcends FDA's medical and scientific expertise; and FDA has no plausible claim to have received from Congress authority to decide it.

To the contrary, as the court of appeals pointed out, such questions must be resolved at a political level, where all relevant concerns can be appropriately weighed. *See* Pet. App. 22a. Prohibition of alcohol occurred by Constitutional amendment. *See* U.S. Const. amend. XVIII. Prohibition of tobacco would be comparably momentous, and should not be open to decision by a single-mission administrative agency.

2. For nearly 60 years before FDA's tobacco rulemaking, the FDCA had been understood by all three branches of government as not granting FDA jurisdiction over tobacco products. The decision below leaves the issue of whether FDA should have jurisdiction over tobacco products where it has always been—with Congress. *See* Pet. App. 52a-53a.

Whether tobacco products should be subjected to the FDCA is the *kind* of issue that, at any time, would have received full and public congressional consideration before any statutory delegation occurred. Yet, Congress is now said to have delegated to FDA in 1938 new jurisdiction over a major sector of the national economy *unwittingly*. On this issue, the legislative process in 1933-38 included no public notice or discussion, no testimony from interested groups, no debate in either House. An interpretation of the statutory product of that process as resulting in a silent and inadvertent inclusion of tobacco products within the FDCA is not consistent with democratic lawmaking.[16]

FDA's position also would override hard-fought legislative processes that have produced the carefully balanced tobacco-specific statutes of the last 34 years. These statutes reflect a political compromise among large and complex interests—relating, *inter alia*, to health, economics, federalism, and informed adult choice. These statutes mark the place where " 'opposing social and political forces have come to rest.' " *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979) (quoting prior decisions).

That this is an issue for Congress is further confirmed by Congress's attentive oversight, and frequent amendment, of both the FDCA and the tobacco-specific statutes.

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[16] Under the Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), FDA (then known as the Bureau of Chemistry in the Department of Agriculture) had taken the position that it had no jurisdiction over tobacco products as customarily marketed. Bureau of Chemistry, U.S. Dep't of Agriculture, Service & Regulatory Announcements, No. 13 (Apr. 2, 1914). Even in broadening the definition of "drug" and adding a parallel definition of "device" in 1938, Congress gave no indication that it intended to change that long-settled position. *Cf. Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 779 (1999) (opinion of O'Connor, J., joined by Rehnquist, C.J., & Kennedy, J.).



In the nearly 61 years since enacting the FDCA in 1938, Congress has amended it 57 times, 25 in the last 19 years. *See* Gerard P. Walsh, Jr., *Federal Food, Drug, and Cosmetic Act With Amendments* iii-iv (GPO 1981) (listing 32 amendments through 1980); 21 U.S.C.A. § 301 Historical & Statutory Notes 33-34 (West Supp. 1998)) (listing 25 amendment since 1980). Congress also has amended its tobacco regulatory program frequently. *See* pp. 8-9, *supra*.

Finally, the settlements between the tobacco industry and the States, which occurred after FDA's tobacco rulemaking, have transformed the environment that prompted FDA to act. The Government is dismissive of the settlements. *See* Pet. 16, 29, n.9. But Congress is the proper governmental body to evaluate them and to decide whether any additional federal controls—by any agency—are now warranted.

3. The court of appeals' decision is correct. Its method of analysis is fully consistent with the two decisions of this Court most relevant to the kind of statutory construction issue presented here.

First, in accordance with *United States v. Fausto*, 484 U.S. 439, 453 (1988), the court performed "the classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination." That task "necessarily assumes that the implications of a statute may be altered by the implications of another statute," and such altering of possible implications is different from a repeal by implication. *Id.*[17]

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[17] It is also different from preemption. *Cipollone* involved preemption of causes of action under *state law*. The instant case involves preclusion by the tobacco-specific statutes of a wholly new interpretation of a *federal* statute. Therefore, the presumption against preemption, which is based on respect for the sovereignty of the States, is inapplicable here.

Second, in determining the FDCA's applicability by considering what its operative provisions require as well as how its definitions may be read, the court properly followed *Gustafson v. Alloyd Co.*, 513 U.S. 561, 569 (1995) ("Although § 10 does not define what a prospectus is, it does instruct us what a prospectus cannot be if the Act is to be interpreted as a symmetrical and coherent regulatory scheme. . . .").

*Fausto* and *Gustafson* make clear that the Government's reliance on the earlier dictum in *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), *see* Pet. 2, 17, is misplaced. The Court there held only that "the literal language" of the FDCA's definition of "drug" does not exclude a therapeutic product that does not touch the body. The court below followed the dictum by treating the FDCA's coverage as being "as broad as its literal language indicates." *Id.* However, the court addressed the language of the *whole* FDCA, whereas FDA's analysis stopped at the definitions. *See* Pet. App. 18a-30a.

*Bacto-Unidisk* cannot displace the analysis mandated at step 1 of *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984), to determine whether the meaning of the statute is clear.

Finally, the *Bacto-Unidisk* dictum does not apply to a situation, like that here, of *multiple* relevant statutes with different purposes. Section 1331 of the FCLAA declares it to be federal policy to protect commerce and the national economy "to the maximum extent consistent with" the provision of warnings on cigarette packages and in cigarette advertising. The policy of protecting commerce and the national economy presumes the continued distribution of tobacco products. The FDCA, however, requires that drugs and devices found unsafe not be distributed at all. *Bacto-Unidisk* does not address how to



harmonize two such statutes where it is asserted that they apply to the same products.

4. Within the framework of multi-statute analysis, the court of appeals proceeded as *Chevron* directs and correctly resolved the issue before it at step 1. The court did not make any of the three errors attributed to it at Pet. 19-27.

First, to ask at step 1 "whether Congress intended to give the FDA jurisdiction over tobacco products," Pet. App. 15a, was merely to ask "whether Congress has directly spoken to the precise question at issue," *i.e.*, whether "the intent of Congress is clear," *Chevron*, 467 U.S. at 842. The court did not try to read the minds of Members of Congress in 1938. Rather, it properly used textual analysis and other traditional tools of statutory construction.

Second, because the court decided this case at *Chevron* step 1, where no deference is due, its refusal to defer to FDA was proper. *See, e.g., Board of Governors of Fed. Reserve Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 368 1986).[18]

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[18] In its summary of general background principles, the court correctly cited *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649-50 (1990), for the proposition that an agency's interpretation of a statute it does not administer is not entitled to deference at *Chevron* step 2. *See* Pet. App. 16a. Because the court decided this case at *Chevron* step 1, however, the issue of deference did not arise; and the court had no occasion to *rely* on *Adams Fruit*. Therefore, the court's reasoning is not circular, as asserted at Pet. 21.

Similarly, contrary to Pet. 22, the court did not decline to defer to FDA on the ground that the agency was seeking to expand its jurisdiction. What the court said was that "ascertaining congressional intent is of particular importance where, as here, an agency is attempting to expand the scope of its jurisdiction." Pet. App. 16a. Ascertaining congressional intent is the task at *Chevron* step 1, where there is no deference; and, under the authorities cited at Pet. App. 16a, the court's statement is correct.

Third, the court's interpretation of the FDCA's operative provisions is faithful to the statutory texts. There is no judicial or FDA interpretation of the FDCA (outside the rulemaking at issue) that permits the continued marketing of any drug or device that has been found unsafe. Contrary to Pet. 23-24, the issue the court decided was not whether FDA's grounds for declining to ban tobacco products are reasonable, but what the FDCA's operative provisions *require*, and whether the relevant statutes, read together and each as a whole, give FDA jurisdiction over tobacco products.[19]

The claim that FDA's "interpretation and application of the complex statutory framework at issue lies at the very core of agency action that is entitled to deference," Pet. 18, misreads *Chevron*. *Chevron* step 1 calls for an independent judicial determination of whether the statute addresses the precise issue, 467 U.S. at 842—here, whether Congress delegated to FDA authority to regulate tobacco products. The Government claims that that issue is conclusively resolved by FDA's finding that tobacco products are "intended to affect" the body. Pet. 20. But that self-aggrandizing approach, not supported by any precedent, would nullify the judicial role in determining at step 1 whether the agency's jurisdictional claim is within the authority granted by Congress.[20] It would "presume a

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[19] Contrary to Pet. 24-25, the court of appeals recognized that an agency may change its interpretation of a statute. *See* Pet. App. 37a n.18. But, in its step 1 analysis, the court also held, correctly, that an agency may not adopt an interpretation that, as here, conflicts with the clear meaning of the statute, as determined from its text and structure.

[20] This extreme delegation argument, first made by the dissent below, *see* Pet. App. 60a, was properly rejected by the court because "[i]t is axiomatic that an administratve agency's power to promulgate legislative regulations is limited to the authority delegated [to it] by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988), quoted at Pet. App. 15a.



delegation of power absent an express withholding of such power," and thus "agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well." *Railway Labor Executives Ass'n v. National Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*).

Resolution of this case at *Chevron* step 1 was especially appropriate in view of the broad issues of policy at its heart. *Cf. Mayburg v. HHS*, 740 F.2d 100, 106-07 (1st Cir. 1984) (Breyer, J.). Here, FDA's assertion of plenary jurisdiction over tobacco products is not the mere filling of a gap to give a statute its congressionally intended scope, but is a reaching out to a wholly different economic sector and a usurpation of a federal policy-making role heretofore exercised solely by Congress. A close examination of the language and structure of the relevant statutes is the proper way to ensure that political accountability remains with Congress, and that agencies do not illegitimately expand their own power.

5. The court of appeals began its analysis by giving weight to a "literal meaning of the statutory definitions" on which FDA relies, taken alone, Pet. App. 18a; but it properly gave greater weight to "the literal definitions in view of the language and structure of the Act as a whole," *id.* at 19a-20a. Here, textual context provides a clear expression of congressional intent. *See, e.g., United Sav. Ass'n v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988) (statutory provision ambiguous in isolation may be clarified by remainder of statutory scheme because only one of the permissible meanings produces a substantive result compatible with the rest of the law). The court examined the FDCA's requirements for genuine medical devices, *see* Pet. App. 23a-30a, and concluded that "the fact that the operative provisions of the Act simply cannot accommodate tobacco products

[*i.e.*, that FDCA jurisdiction leads to a ban] is a clear indication of congressional intent" not to authorize FDA to regulate them, *id.* at 31a. In sum, as FDA, itself, long recognized, *see* p. 11 & n.9, *supra*, the FDCA was not designed to accommodate a product with the kind of regulatory history and public perception that tobacco had even by the 1930s, or to address the kinds of issues tobacco raises. Indeed, to permit tobacco products to be marketed *under the FDCA* even though FDA has found them unsafe would be to undermine the FDCA's protections against genuine drugs and devices that are unsafe.

Even in 1938 there was no understanding that cigarettes were "safe" as that term is used in the FDCA;[21] by 1964 the Government's position was that cigarettes have foreseeable "habituat[ing,]" and "pharmacological" effects on the body; and in 1970 Congress required that cigarettes be labeled as "dangerous," their effects on the body having been established by the Surgeon General. *See* pp. 3-4, *supra*. In contrast, since 1938, the FDCA has prohibited the marketing of any drug or medical device that is "dangerous to health." Pub. L. No. 75-717, § 502 (j), 52 Stat. 1040, 1051 (1938), 21 U.S.C. § 352(j). Thus, if cigarettes had been subject to the FDCA, FDA would have had to ban them in 1938 or 1964, but no later than 1970, as "not show[n to be] safe," 21 U.S.C. § 355(d)(2), and as "dangerous," *id.* at § 352(j). However, FDA took no such action.

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[21] For all purposes of the FDCA, a drug or medical device is "safe" when its therapeutic benefits outweigh its risks. Pet. App. 20a-22a. Thus, for example, cancer chemotherapeutic drugs are highly toxic but nevertheless "safe"; a cold remedy with the identical toxicity would be "unsafe." Therefore, FDA's express finding that tobacco products are "unsafe," *see* note 22, *infra*, as a finding not merely that they present risks or are toxic, but that the risks they present are not outweighed by any therapeutic benefits.



In its tobacco rulemaking, FDA found that tobacco products have foreseeable bodily effects. *See* Pet. 3-4. Under FDA's new theory of "intended use," that is a jurisdictional finding, which could have been made at any time since 1964 or even 1938. FDA also found that tobacco products are "unsafe" and "dangerous."[22] Under the FDCA, those findings would require a ban. *See* Pet. App. 20a-29a.

The Government states that a ban would be contrary to the public health and absurd for other reasons as well. *See* Pet. 8-9. A ban by FDA would also be contrary to the premise of the tobacco-specific statutes, including FCLAA § 1331, which FDA ignored.[23]

After considering the whole FDCA, the court below considered the tobacco-specific statutes. *See* Pet. App. 39a-52a. They demonstrate, through enacted legislation, how Congress intended tobacco products to be regulated with respect to health, underage access, and advertising. Those statutes provide the context for interpretation of the FDCA on the specific issue presented here. *Cf. Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 775-78 (1999); *Dunn v. CFTC*, 519 U.S. 465, 475 (1997).

In enacting the tobacco-specific statutes, Congress precluded any new "implication" (even if otherwise permis-

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[22] 61 Fed. Reg. 44,396, 44,412 (1996); *see also id.* at 44,405; 60 Fed. Reg. 41,314, 41,349 (1995).

[23] The Government quotes the dissent's argument that "[h]ow the FDA has chosen to regulate tobacco has no bearing on the question of whether that agency has the authority to regulate it at all[.] It is no argument to say that the FDA can do nothing because it could have done more." Pet. 24 (quoting Pet. App. 60a-61a). That is not the court's analysis. The analysis is that, if FDA has jurisdiction, it *must* ban tobacco products because it has found them unsafe; and *any* set of regulations short of a ban (not just FDA's current regulations) would be invalid under the FDCA. The dissent disregards the FDCA's operative provisions.

sible), *cf. Fausto*, 484 U.S. at 453, that the FDCA silently delegated to FDA authority to decide to assert jurisdiction over tobacco products and to ban them—the very result Congress rejected in 1965, *see* p. 6, *supra*. "To find authority so explicitly withheld is not merely to disregard in a particular instance the clear will of Congress. It is to disrespect the whole legislative process and the constitutional division of authority between President and Congress." *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 609 (1952) (Frankfurter, J., concurring).

6. The contention that the FDCA's definitions apply to "all products not expressly exempted," Pet. 16, is obviously wrong. That interpretation would, for example, destroy much of the jurisdiction of Consumer Product Safety Commission ("CPSC"). FDA asserts that every product that foreseeably affects the structure or functioning of the body is a "drug" or "device." However, many consumer products regulated by the CPSC foreseeably affect the structure or functioning of the body (*e.g.*, thermal clothing, air conditioners). Indeed, the CPSC regulates products for the very purpose of reducing their foreseeable harmful effects; but the Consumer Product Safety Act exempts from its coverage "drugs" and "devices," 15 U.S.C. § 2052(a)(1)(H).

Congress has not given FDA limitless jurisdiction and a roving commission to protect the public health as it sees fit. As this Court observed in *Rodriguez v. United States*, 480 U.S. 522, 525-26 (1987) (*per curiam*) (emphasis in original):

> [N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law.



The FDCA's detailed provisions carefully delineate FDA's authority to regulate specified categories of products. The safety of other categories of products (*e.g.*, automobiles, airplanes, tobacco products, consumer products generally) is addressed by other statutes.[24]

7. The decision below restores the balance between federal and state roles with respect to tobacco products, which FDA disturbed without a clear statement by Congress. *See, e.g., Gregory v. Ashcroft*, 501 U.S. 452, 460-61 (1991).

Defining and enforcing restrictions on underage access to tobacco products are traditional functions of the States. *See* p. 3, *supra*. FDA's regulations would supersede such state restrictions and wrest the lead enforcement role from the States. *See* 21 C.F.R. § 897.14. Indeed, under 21 U.S.C. § 360k, all relevant state laws that are different from or in addition to FDA's regulations are preempted; on application by a State, FDA may waive preemption, but waiver is discretionary. *Id.*

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[24] The absence of an express exemption in the FDCA for tobacco products is fully explained by HEW's and FDA's testimony to Congress in 1964-65. *See* pp. 5-6, *supra*. Some matters are so clear that no express provision is needed. *See, e.g., NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 283 (1974); *Argentine Republic v. Amerada Hess Shipping Corp.*, 488 U.S. 428, 437 (1989) ("we doubt that even the most meticulous draftsman would have concluded that Congress also needed to amend *pro tanto* the [earlier statute]").

The Government's citation of 21 U.S.C. § 321(ff)(1), *see* Pet. 17, 22, is inapposite. In the dietary supplement legislation, Pub. L. No. 103-417, § 3, 108 Stat. 4325, 4327 (1994), Congress excluded tobacco from the new definition of "dietary supplement." The subject before Congress in 1994 was dietary supplements. Congress merely excluded from that legislative process the contending interests on the unrelated question of FDA jurisdiction over tobacco products. From Congress's limited action in 1994, no inference one way or the other can properly be drawn with respect to that unrelated question.

Under FDA's regulations, every improper sale or failure to verify the age of a purchaser in a local convenience store or gas station is a federal offense, 21 C.F.R. § 897.1(b); 21 U.S.C. § 331(b),(k), punishable by prosecution in federal district court, *id.* § 333(a)(1), or by civil penalty imposed by FDA and reviewable in the federal courts of appeals, *id.* § 333(g). The creator of this potentially massive expansion of federal civil and criminal jurisdiction is not Congress, but FDA.[25]

There is no clear congressional statement authorizing FDA to supersede state laws on underage access, to create *federal* criminal or civil penalty liability for violations of restrictions on underage access, or to shift the lead enforcement role from the States to the federal government. To the contrary, the 1992 tobacco statute seeks to strengthen the State role. *See* pp. 8-9, *supra*. That some States may welcome this transfer of responsibility to the federal government does not provide Congressional sanction for the federalization of traditional state functions.

## CONCLUSION

The petition for a writ of certiorari should be denied.

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[25] The expansion of federal jurisdiction is not merely theoretical. FDA has already initiated civil penalty proceedings that allege local violations of FDA's sales and age-verification requirements. Telephone Conversation with Deputy Branch Chief, FDA Dockets Management Branch (Feb. 22, 1999).

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